K082274

Jiangyin East China Medical Technology Co., Ltd.
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510(k) Summary

Device

Trade name: **HAIDA HD 11** manual Wheelchair

Common name: Manual Wheelchair

AUG 19 2008

Classification name: Mechanical wheelchair

Medical specialty (Panel): Physical Medicine Device

Regulation number: 890.3850

Product Code: 89IOR

Classification: Class I

Predicate devices

Solara (K012370)/ Invacare Corporation

AIDC 8500(K043332)/ Aerospace Industrial Development Corporation (AIDC)

Intend use of device

It is intended use to provide mobility to physically challenged persons limited to a sitting position on the flat and firm terrain in outdoor or indoor.

Device description:

It consists of a rigid, mechanical, steel frame and nylon upholstery back and seat. It has two 24" rear wheels and two 8" front casters for turning and maneuverability.

Substantial equivalence:

It is substantially equivalent to the legal products in USA. They have the same technological characteristics and intended use of the devices.

There are minor differences in performance specifications of the manual wheelchairs, these differences do not alter the intended use function and use of the device, nor do they raise any new questions pertaining to safety or effectiveness.

Non-Clinical testing

It meets the applicable performance requirements as specified in ANSI/RESNA WC Vol. 1 Sec. 1, Sec.5, Sec.7, Sec.8, Sec.15, Sec.16 and California Bureau of Home Furnishings 117.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Jiangyin East China Medical Technology Company., Ltd
% Junnata Chang, Ph.D.
14F-2 NO. 1 Lane 25
Zhuangjing Road
Banqiao,
China (Taiwan) 220

AUG 19 2008

Re: K082274
Trade/Device Name: HAIDA HD 11 Manual Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair.
Regulatory Class: Class I
Product Code: IOR
Dated: July 25, 2008
Received: August 11, 2008

Dear Dr. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): _____

Device Name: **HAIDA HD 11 manual wheelchair**

Indications for Use:

To provide mobility to physically challenged persons limited to a sitting position on the flat and firm terrain in outdoor or indoor.

Prescription Use _____ Over-The-Counter Use __X__

(Part 21 CFR 801 Subpart D) AND/OR

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1 of 1

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number k082274

(Posted November 13, 2003)